

AMENDMENTS TO THE CLAIMS:

Please cancel claims 11 and 44 without disclaimer or prejudice and amend the claims as follows:

1.(Currently Amended) A process of purifying citalopram, either in racemic or enantiomeric form, which process comprises:

(i) providing a crude mixture comprising citalopram, either in racemic or enantiomeric form, dissolved in a water immiscible organic solvent, and which mixture also includes one or more citalopram derivatives which are present as citalopram impurities;

(ii) washing said crude mixture with at least one dilute aqueous solution of a polybasic acid of editic acid, either in free form or as a partial alkali metal salt, so as to separate said citalopram from citalopram impurities present in said crude mixture, said solution having a strength in the range of 0.5% to 6%; and

(iii) where required converting citalopram free base, separated from citalopram impurities further to step (ii), to a pharmaceutically acceptable salt.

2.(Currently Amended) A process according to claim 1, which comprises carrying out an initial washing of the crude mixture with at least one dilute aqueous solution of a the polybasic acid, either in free form or as a partial alkali metal salt, so as to remove citalopram impurities from the crude mixture, and subsequently washing the residual crude mixture with at least one further dilute aqueous solution of a polybasic acid of editic acid, either in free form or as a partial alkali metal salt, said further solution having

a strength in the range of 4% to 25%, with the proviso that the strength is greater than the strength of the polybasic acid used in the initial washing step, so as to separate citalopram, either in racemic or enantiomeric form, from the impurities remaining in the crude mixture, by extraction of citalopram, as a salt formed with the polybasic acid, into an aqueous phase.

3. (Currently Amended) A process according to claim 2, wherein the impurities removed from the crude mixture by the initial washing with said at least one dilute aqueous solution of a the polybasic acid have a basicity of greater than the basicity of citalopram.

4. (Original) A process according to claim 3, wherein the impurities remaining in the crude mixture further to the initial washing with said at least one dilute aqueous solution of said polybasic acid have a basicity of less than the basicity of citalopram.

5. (Previously Presented) A process according to claim 2, wherein a base is added to the aqueous phase containing citalopram as a salt of the polybasic acid, in an amount sufficient to liberate citalopram free base which is then extracted into an organic solvent.

6. (Currently Amended) A process of purifying citalopram, either in racemic or enantiomeric form, which process comprises:

(i) providing a crude mixture comprising citalopram, either in racemic or enantiomeric form, dissolved in a water immiscible organic solvent, and which mixture also includes one or more citalopram derivatives which are present as citalopram impurities;

(ii) washing said crude mixture with at least one dilute aqueous solution of a polybasic acid of editic acid, either in free form or as a partial alkali metal salt, so as to remove citalopram impurities from the crude mixture, said solution having a

strength in the range of 0.5% to 6%;

(iii) washing the residual crude mixture obtained further to step (ii) with at least one further dilute aqueous solution of a polybasic acid of editic acid, either in free form or as a partial alkali metal salt, said further solution having a strength in the range of 4% to 25% with the proviso that the strength is greater than the polybasic acid used in the washing of step (ii), so as to separate said citalopram from impurities remaining in said residual crude mixture, by extraction of citalopram, as a salt formed with the polybasic acid, into an aqueous phase and optionally washing the resulting aqueous phase with an organic solvent;

(iv) adding a base to the aqueous phase in an amount sufficient to liberate citalopram free base and extracting the liberated citalopram into an organic solvent;

(v) optionally re-extracting citalopram free base from the organic extract obtained further to step (iv) by washing with at least one further dilute aqueous solution of a polybasic acid of editic acid, either in free form or as a partial alkali metal salt, so as to extract citalopram, as a salt formed with the polybasic acid, into an aqueous phase and adding thereto a base in an amount sufficient to liberate citalopram free base and further extracting the liberated citalopram into an organic solvent; and

(vi) where required converting the free base obtained further to step (iv) or (v) to a pharmaceutically acceptable salt thereof.

7. (Previously Presented) A process according to claim 1, wherein the water immiscible solvent employed in step (i) is selected from the group consisting of toluene,

ethyl acetate, hexane and methylene dichloride.

8. (Original) A process according to claim 7, wherein the water immiscible solvent is toluene or ethyl acetate.

9. (Currently Amended) A process according to claim 1, wherein the polybasic acid is selected from the group consisting of tartaric acid, oxalic acid, fumaric acid, citric acid and edetic acid, which can either be employed in free form, or as a partial alkali metal salt.

10. (Original) A process according to claim 9, wherein the alkali metal salt is the sodium salt.

11. (Cancelled).

12. (Currently Amended) A process according to claim [[11]] 10, wherein said ~~edetic acid~~ alkali metal salt is employed as disodium edetate.

13. (Previously Presented) A process according to claim 6, wherein the initial washing of the crude mixture with said at least one dilute aqueous solution of said polybasic acid of step (ii) removes impurities from the crude mixture having higher basicity compared to citalopram.

14. (Previously Presented) A process according to claim 3, wherein the initial washing removes one or more of the following impurities if present in the crude mixture: 5- carboxamide citalopram, N-desmethyl citalopram, desfluoro citalopram, 4-[4-(dimethylamino)-1-(4'-fluorophenyl)-1-hydroxybutyl]-3-(hydroxymethyl)-benzonitrile and/or 5-formyl citalopram.

15. (Currently Amended) A process according to claim 2, wherein the polybasic acid is employed as the salt, disodium edetate, and wherein subsequent washing separates citalopram from the residual crude mixture, whereby citalopram as a salt formed with disodium edetate is extracted into an aqueous phase.

16. (Previously Presented) A process according to claim 6, wherein the impurities remaining in the residual crude mixture subsequent to the initial washing have a basicity of less than citalopram.

17. (Previously Presented) A process according to claim 4, wherein the impurities remaining in the residual crude mixture subsequent to the initial washing are selected from the group consisting of descyano citalopram, 5-chloro citalopram and 5-bromo citalopram.

18. (Previously Presented) A process according to claim 2, wherein the subsequent washing is carried out at a temperature in the range of 40 to 80°C.

19. (Previously Presented) A process according to claim 5, wherein said base comprises an aqueous alkali metal hydroxide solution.

20. (Previously Presented) A process according to claim 19, wherein the base is aqueous sodium hydroxide or potassium hydroxide.

21. (Previously Presented) A process according to claim 5, wherein the

liberated citalopram free base is extracted from the aqueous phase into ethyl acetate.

22. (Previously Presented) A process according to claim 1, which includes converting citalopram free base to a pharmaceutically acceptable salt of citalopram.

23. (Original) A process according to claim 22, wherein the pharmaceutically acceptable salt is selected from the group consisting of the hydrobromide, hydrochloride and oxalate.

24. (Previously Presented) A process of preparing citalopram, either in racemic or enantiomeric form, by ring closure of 4-[4-(dimethylamino)-1-(4'-fluorophenyl)-1-hydroxybutyl]-3(hydroxymethyl)-benzonitrile, dissolving the resulting citalopram, together with one or more citalopram derivatives which are present as citalopram impurities, in a water immiscible organic solvent so as to provide a crude mixture thereof, and subjecting the resulting crude mixture to a purification process according to claim 1.

25. (Previously Presented) A process of preparing citalopram, either in racemic or enantiomeric form, by conversion of 1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-5-bromo phthalane to the corresponding cyano derivative, namely citalopram, dissolving the resulting citalopram, together with one or more citalopram derivatives which are present as citalopram impurities, in a water immiscible organic solvent so as to provide a crude mixture thereof, and subjecting the resulting crude mixture to a purification process according to claim 1.

26-38. (Canceled).

39. (Currently Amended) A process of claim 1 wherein said polybasic acid salt is disodium edetate.

40. (Currently Amended) The process of claim 2 wherein said at least one further dilute aqueous solution of a polybasic acid salt is an aqueous solution of disodium edetate.

41. (Currently Amended) The process of claim 6 wherein the polybasic acid salt of step (ii) is disodium edetate.

42. (Currently Amended) The process of claim 6 wherein the polybasic acid salt of step (iii) is disodium edetate.

43. (Currently Amended) The process of claim 6 wherein step (v) re-extracts citalopram free base from the organic extract by washing with at least one further dilute aqueous solution of a polybasic acid salt of disodium edetate.

44. (Cancelled) .